REMARKS

By the foregoing amendments to the claims, claims 18, 23 and 24 have been amended. Applicants note that no new matter has been added. Upon entry of this amendment, claims 1-7 and 13-25 are currently pending while claims 1-17, 20, and 25 are withdrawn from consideration.

Formal Matters

Applicant acknowledges that the Examiner has withdrawn newly added claim 25 from consideration because it allegedly is directed to a method that is distinct from the method claimed in claim 18. Applicants respectfully traverse this restriction.

In traversing this restriction, Applicant notes that the Office has not established that the disclosed inventions are distinct and unrelated. Applicant's traversal is on the grounds that while the inventions may be distinct or unrelated, there should not be an undue search burden to consider the inventions together. The MPEP states that if the search and examination of all the claims in an application *can be made without serious burden*, the Examiner must examine them on the merits, even though they include claims to independent or distinct inventions. (MPEP 803.)

Applicant respectfully submits that a search for the subject matter of claim 18 would appear to overlap with a search for the subject matter of claim 25, and that it would appear that inclusion of the claim 18 and its dependent claims with claim 25 should not result in an undue search burden. Applicant respectfully requests that the Examiner reconsider the restriction requirement.

Applicant notes with appreciation that the previous rejections under 35 U.S.C. § 102(b) have been overcome in view of Applicant's amendment submitted on September 26, 2008. However, the Office raises new rejections.

Claim Rejections – 35 U.S.C. § 112

The Office Action rejects claims 18, 19, and 21-24 under 35 U.S.C § 112, first paragraph, for allegedly failing to comply with the written description requirement.

Applicant respectfully submits that the foregoing amendments render this rejection moot.

The Office Action rejects claim 24 under 35 U.S.C § 112, second paragraph, for allegedly being indefinite with respect to the recitation "standard sized bathtub."

With the current amendment, this rejection has been addressed and Applicant respectfully requests its withdrawal.

Claim Rejections – 35 U.S.C. § 103

The Office Action rejects claims 18, 19, and 21-24 under 35 U.S.C § 103 (a) as being obvious over the combination of U.S. Patent No. 5,780,047 ("'047"), U.S. Patent No. 5,342,535 ("'535"), U.S. Patent Application Publication No. 2001/0036489 ("'489"), and U.S. Patent No. 6,083,996. The Action asserts that the combination of these documents renders claims 18 and 19 obvious.

This rejection is respectfully traversed.

Initially, Applicant notes that the Office concedes that US'047 does not teach ibuprofen (see Office Action, page 6, first full paragraph). In order to cure this deficiency, the Office relies on US'489 or US'996. Applicant respectfully disagrees with the Office that the substitution of one anti-inflammatory ingredient with ibuprofen would have been obvious to one of ordinary skill in the art. In this regard, Applicant points out that there would be no reasonable expectation of success if ibuprofen would be substituted for the anti-inflammatory ingredient disclosed in US'047.

Applicant notes that the primary document US'047 teaches a gel patch. Even assuming that one of ordinary skill would have a reason to modify the gel patch and add ibuprofen as an active ingredient, the resulting formulation would not have a reduced transdermal delivery potential. In this regard, it is resepectfully pointed out that addition of ibuprofen to a gel patch

according to US'047 would cause the ibuprofen to undergo a reaction with propylene glycol to form an ester at elevated temperatures, such as the temperatures discussed in the Formulation Examples in columns 11 and 12 of US'047. As a result, the ibuprofen would be chemically altered by a covalent bond between the ibuprofen acid group and alcohol groups of propylene glycol. Applicant notes that such reaction would not occur with the anti-inflammatory ingredient that is disclosed in US'047 because this ingredient, namely methyl salicylate, cannot form an ester because it lacks an acid group.

As a result, the modified ibuprofen ester would not be suitable for use in transdermal delivery in the formulation of US'047. This is completely different from the present invention, wherein ibuprofen in the claimed formulation does not form an ester or a covalent bond with another material.

Therefore, even assuming that a person of ordinary skill in the art would have a reason to replace the active ingredient of U.S.'047 with the ibuprofen from US'489 or US'996, the skilled person would not have a reasonable expectation of success that ibuprofen could be employed in transdermal administration. Therefore, if anything, U.S.'047 teaches away from the presently claimed invention.

In this regard, Applicant notes that claim 19 recites a tablet, which is not a gel patch. Applicant respectfully disagrees with the Examiner that the tablet of the present application and the gel patch of US'047 would be interchangeable because the effervescent tablet requires a dry preparation process while the gel patch of US'047 teaches a wet preparation process.

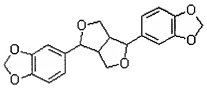
Addressing the Action's assertion of effervescence in the asserted documents, Applicant respectfully disagrees with the Examiner, that US'047 provides a basis for effervescence in the formulation. On page 8 of the Office Action, beginning at the end of line 6, the Examiner states that "it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a product that can be poured or dissolved in bathwater to reli[e]ve pain and stiffness and comprises anti-inflammatory agents, permeation enhancer, sodium bicarbonate and citric acid as disclosed by US '047, and deliver the ingredients in an effervescent tablet compris[ing] specific amounts of sodium bicarbonate and citric acid as disclosed by US'535

because US'535 teaches such effervescent tablet." Applicant respectfully disagrees and requests reconsideration.

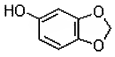
Applicant respectfully submits that even assuming that US'047 discloses sodium bicarbonate and citric acid as ingredients of the formulation, this does not amount to a disclosure or suggestion of an effervescent formulation. Applicant submits that one of ordinary skill upon review of US'047 would know that the resulting patch would not be effervescent even if sodium bicarbonate and citric acid were used during formulation. Even assuming that one of ordinary skill would employ sodium bicarbonate and citric acid, there would be no effervescence remaining in the finished patch because it is prepared by a wet process (see Formulation Examples in columns 11 and 12 of US'047) during which any sodium bicarbonate would react with any citric acid and loose its effervescent potential. In order to have an effervescent formulation, the preparation process must be a dry process. However, such process is not disclosed in US'047. Accordingly, US'047 does not disclose an effervescent formulation and the ordinarily skilled person would have no reason to refer to US'535. Accordingly, the rejection based on this combination should be withdrawn.

Moreover, even assuming, for the sake of argument, that the combination of the documents were proper, Applicant respectfully submits one of ordinary skill in the art would not arrive at the invention as a result of the teachings of these documents.

In the instant application, Applicant submits that the presently claimed invention includes clarified sesame seed oil. Sesame seed oil has different proportions of monounsaturated and polyunsaturated fatty acids that are common to the other vegetable and nut oils. However, unique to clarified sesame seed oil is the presence of unsaponifiables such as two natural antioxidants called sesamin and sesamol. There is a third unsaponifiable species called sesamoline which in the present invention also may assist in ibuprofen transdermal absorption though the skin.



Sesamin



Sesamol

Not intending to be held to any one theory, Applicant understands that it is the additional presence of sesamin and sesamol that help dissolve the ibuprofen into the sesame oil and allow the dissolution to a super-saturation point. The term super-saturation refers to a solution that contains more of the dissolved material than could be dissolved by the solvent under normal circumstances. Sesamin and sesamol contain a high degree of polarity and conjugated double bonds similar to ibuprofen that would enable solubilization on the classic theory of "like dissolves like." Unexpectedly, Applicant's presently claimed formulation provides a formulation that contains an oil phase containing supersaturated ibuprofen. It is this combination of a specific oil and a specific active ingredient (recited in the claims of this application) that results in a supersaturated mixture with enhanced transdermal delivery potential. Applicant once again emphasized that one of ordinary skill would not expect this successful result.

Accordingly, Applicant respectfully submits that the presently claimed invention is unexpectedly successful, and that in view of this, in addition to the foregoing, the rejection should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant submits that all of the claims are patentably distinct over the cited art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue. Favorable consideration with early allowance of all of the pending claims is most earnestly requested.

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,
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July 7, 2009
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